REMARKS

Claims Objection

The Office objects to claim 2 for redundancy, Applicant's representative (hereafter "Applicant") has carefully considered the objection. Applicant does not believe that the objection is warranted and does not know of an amendment that could be made that would address the objection.

Rejection Under 35 U.S.C. § 103(a)

The Office also rejects both pending claims, claims 1 and 2, for obviousness over Pittenger et al. (WO 99/03973; hereinafter "Pittenger") in view of Bruder et al. (WO 97/39104; hereinafter "Bruder") or Abatagelo et al. (U.S. Patent No. 6,482,231; hereinafter "Abatangelo"), as evidenced by Ha et al. (U.S. Patent Application Publication No. 2005/0118714; hereinafter "Ha"). This rejection is in error and should be withdrawn.

At the outset, Applicant wishes to correct the record on one point: the copy of the Declaration of Morey Kraus (the "Declaration") submitted in this case on October 24, 2007, was provided at the request of the Examiner; that Declaration had been submitted in a related case, U.S.S.N. 09/985,335, to remove Erices et al. (British J. Haematol. 109:235-242, 2000; hereinafter "Erices") as a prior art reference as to the claims in that case, which are directed to cells derived from human cord blood and designated USSCs. In the present case, the claims are not directed to the cells themselves, but rather to their use in cardiac muscle regeneration. Thus the Declaration, which does not mention cardiac regeneration, does not remove Erices from the prior art in the present case. Applicant cannot demonstrate that the cells of Erices, which are derived from cord blood, are different from the USSCs used in the claimed cardiac regeneration method; the Abatagelo, Bruder, and Ha references require no discussion.

The issue in the present case is not whether the USSCs used in the claimed method were in the prior art, but whether it would have been obvious to use those cells for cardiac muscle repair. As was discussed during the in-person interview held on October 16, 2007, nothing in the prior art suggests the use of cord blood-derived USSCs for cardiac muscle repair, let alone provides a reasonable likelihood of success in using USSCs for this purpose.

Erices does not teach or suggest that mesenchymal progenitor cells (MPCs) from cord blood could successfully be used for cardiac muscle repair; Erices only states that the cells have osteogenic or adipogenic potential (see p. 240, col. 2). There is no suggestion in Erices that the disclosed cells might have the very different potential to become myogenic cells, much less cardiomyogenic cells, as claimed in the present application.

Pittenger does not remedy this deficiency in Erices. First, it is already of record, and conceded by the Examiner, that Pittenger's mesenchymal stem cells, which are derived from bone marrow, are different from the cord blood-derived USSCs of the present invention. Therefore, the only issue is whether Pittenger's disclosure of the use of the different bone marrow-derived stem cells for cardiac muscle repair would render obvious the use of Applicant's admittedly different cord blood-derived USSCs for cardiac muscle repair. For that claimed invention to have been obvious, there must be in the prior art something to suggest the invention i.e., it must have been obvious to try and there must have been a reasonable likelihood of success. Neither condition is satisfied in the present case.

As is discussed above, the one reference that describes cord blood-derived progenitor cells, Erices, only describes two possible differentiation pathways for the cells, yet both are far removed from cardiomyogenesis. This is significant because it demonstrates that the Erices authors were willing to speculate about the differentiation potential of the described cells, yet, tellingly, they made no mention of cardiomyogenesis.

Furthermore, even if the claimed method would have been obvious to try in view of Pittenger. Pittenger contains nothing that would have provided a reasonable likelihood of success, as is required for a finding of obviousness. This legal standard was set out by the Federal Circuit in *In re O'Farrell* (853 F.2d 894 (Fed. Cir. 1988); 7 U.S.P.Q.2d (BNA) 1673). More recently, the *O'Farrell* standard was reapplied by the United States Supreme Court in *KSR International Co. v. Teleflex Inc.* (127 S. Ct. 1727, 1739–40 (2006); 82 U.S.P.Q.2d (BNA) 1385; emphasis added), which held that a combination that is obvious to try might be obvious under § 103 where there are "a finite number of identified, *predictable* solutions" and where "a person of ordinary skill has good reason to pursue the *known options* within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill

and common sense." Under the facts of this case, the prior art provided neither predictable solutions nor reasons to pursue other options.

The field of the invention is the use of cells to treat a medical condition. There can be no disagreement as to whether this field is unpredictable; indeed, the MPEP, § 2164.03, refers to "cases involving unpredictable factors, such as most chemical reactions and physiological activity...." Of course, reasonable likelihood of success varies inversely with unpredictability.

Consistent with the discussion above, therapies using a different type of stem cell have in fact been proven to be unpredictable and prone to failure. One of many examples is reported by Nussbaum et al. ("Transplantation of Undifferentiated Murine Embryonic Stem Cells in the Heart: Teratoma Formation and Immune Responses," *The FASEB Journal* 21:1345-1357, 2007; a copy is enclosed). In that paper, the authors report experiments in which embryonic stem cells (ES cells) were administered to mice with the objective of cardiac muscle repair. Rather than achieving this result, however, the authors observed the medically disastrous formation of a teratoma. Clearly, success in cardiac muscle repair using one stem cell type is not predictive of success for any other stem cell type. Moreover, Mareschi et al. (*Hematologica* 86:1099-1100, 2001; a copy is enclosed), which was published after Erices, clearly demonstrates that there was still disagreement in the art about whether cord blood mesenchymal stem cells even existed, much less whether they could be administered in a manner similar to that described for bone marrow mesenchymal stem cells.

Unlike the authors of the above-cited papers, the present inventor succeeded in identifying cord blood mesenchymal stem cells and achieving cardiac muscle repair using these different stem cells. This success could not have been predicted; the experiment had to be performed.

For the reasons given above, Applicant respectfully submits that the rejection of claims 1 and 2 for obviousness should be withdrawn.

CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance, and such action is requested.

Enclosed is a petition to extend the period for replying to the Office Action for two months, to and including April 8, 2008, and an authorization to charge the fee required by 37 C.F.R. § 1.17(a) of $230.00 to Deposit Account No. 03-2095

If there are any other charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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